

REMARKS

Claims 1-5, 7-19, 21 and 22 are presented for reconsideration and further examination in view of the following remarks. Claims 2-4 and 14 were withdrawn by the Examiner following Applicants' election responsive to a Restriction Requirement. By this Response and Amendment, claims 1-5, and 7-19 have been amended, claims 6 and 20 have been canceled and claims 21 and 22 are newly presented.

In the outstanding Office Action, the Examiner rejected claims 1, 5-13 and 15-20 under 35 U.S.C. 112, second paragraph as being indefinite; rejected claims 1, 5-7, 9-11, 15 and 20 under 35 U.S.C. § 103(a), as being unpatentable over U.S. Patent No. 4,014,318 to Dockum et al. (hereinafter referred to as "Dockum et al.") in view of U.S. Patent No. 6,450,773 to Upton (hereinafter referred to as "Upton"); rejected claims 16 and 17 under 35 U.S.C. § 103(a), as being unpatentable over Dockum et al. in view of Upton as applied to claim 1 above, and further in view of U.S. Patent No. 4,741,736 to Brown (hereinafter referred to as "Brown"); rejected claims 18 and 19 under 35 U.S.C. § 103(a), as being unpatentable over Dockum et al. in view of Upton as applied to claim 1 above, and further in view of U.S. Patent No. 4,270,532 to Franetzki et al. (hereinafter referred to as "Franetzki et al."); and objected to claim 7 for informalities and required correction.

Claims 1-5 and 7-19 have been amended, claims 21 and 22 added, and claims 6 and 20 canceled, for the sole reason of advancing prosecution. Applicants, by amending or canceling any claims herein, make no admission as to the validity of any rejection made by the Examiner against any of these claims. Applicants reserve the right to reassert the original claim scope of any claim amended or canceled herein or in a previous Response, in a continuing application.

Support for the amended claims may be found throughout the original specification,

claims and figures as filed. The claims have been amended to delete a reference to figure numbers, correct capitalization and grammatical typographical errors, and to further conform the claims to U.S. patent practice, as suggested by the Examiner. Amended claim 1 incorporates the subject matter of now canceled claim 20; the amended claim language is supported literally on page 15, lines 8-10, of the original specification (Publication No. WO 2004/044424 of priority document PCT/IL2003/000947). Amended claims 12 and 13 rewrite the Examiner indicated Allowable Subject Matter in independent form, as suggested by the Examiner. Newly presented claims 21 and 22, dependent from claim 1, recite further features of the anti-free flow mechanism of amended claim 1. Support for the newly presented claims may be found at least on page 15, lines 11-18, of the original specification.

Thus, it is respectfully submitted that the above amendments introduce no new matter within the meaning of 35 U.S.C. § 132.

Interview Summary

Applicants thank Examiner Freay for the courtesy extended to Applicants' Representative during a telephone Interview on May 15, 2009. In the Interview, the Examiner explained that he considered the check valve shown in Fig. 12 of Dockum et al. to fall within the broadest interpretation of the "anti-free flow device" recited in original claim 20 of the instant application.

Objections to the claims

The Examiner objected to claim 7 for informalities and required correction. Specifically, the Examiner objected to the phrasing of claim 7 and required correction.

Response

As discussed above, claim 7 has been amended in accordance with the Examiner's suggestion. Specifically, the claim phrasing "wherein one or more valves is" has been replaced with "wherein one or more valves are." Applicants respectfully submit that the above amendment obviates the Examiner's objections to the claims and request reconsideration and an indication of the same.

Rejections to the claims under 35 U.S.C. § 112, second paragraph

Claims 1, 5-13 and 15-20 were rejected under 35 U.S.C. 112, second paragraph, for indefiniteness. Specifically, the Examiner stated that "the claims are vague and indefinite because they make reference to the figures in the last line of the claim," and that the claim 6 term "preloaded" was unclear.

Response

As discussed above, by this Response and Amendment, claim 6 has been canceled without prejudice or disclaimer thereto. Therefore this rejection is moot.

Claim 1, 5, 7-13 and 15-20 have been amended or depend from amended claims; as amended, Applicants respectfully traverse the rejections thereto.

Applicants have amended claim 1 to remove the Examiner-rejected reference to the figure. Claims 5, 7-13 and 15-20 make no "reference to the figures in the last line of the claim" rejected by the Examiner in claim 1; Applicants assume that claims 5, 7-13 and 15-20 were rejected under 35 U.S.C. 112, second paragraph, due solely to their dependency from claim 1.

Accordingly, Applicants respectfully submit that the present claims are definite under the meaning of 35 U.S.C. 112, that the above discussed amendments obviate the rejections and request reconsideration thereto.

Rejections to the claims under 35 U.S.C. § 103(a)

The Examiner rejected claims 1, 5-7, 9-11, 15 and 20 under 35 U.S.C. § 103(a), as being unpatentable over Dockum et al. in view of Upton; rejected claims 16 and 17 under 35 U.S.C. § 103(a), as being unpatentable over Dockum et al. in view of Upton as applied to claim 1 above, and further in view of Brown; rejected claims 18 and 19 under 35 U.S.C. § 103(a), as being unpatentable over Dockum et al. in view of Upton as applied to claim 1 above, and further in view of Franetzki et al.

Response

By this Response and Amendment, claims 6 and 20 have been canceled without prejudice or disclaimer to the contents thereto. Accordingly, the rejections thereto are moot.

Applicants traverse the remaining rejections as all of the features of the presently claimed subject matter are not disclosed, taught or suggested by the cited prior art of record.

To establish a *prima facie* case of obviousness, the Examiner must establish that the prior art references teach or suggest all of the claim features. *Amgen, Inc. v. Chugai Pharm. Co.*, 18, USPQ2d 1016, 1023 (Fed. Cir. 1991); *In re Fine*, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988); *In re Wilson*, 165 USPQ2d 494, 496 (CCPA 1970).

A *prima facie* case of obviousness must also include a showing of the reasons why it would be obvious to modify the references to produce the present invention. *See Dystar*

Textilfarben GMBH v. C. H. Patrick, 464 F.3d 1356 (Fed. Cir. 2006). The Examiner bears the initial burden to provide some convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings. *Id.* at 1366.

Overview

Amended independent claim 1 recites, *inter alia*, a pump for generating fluid flow in an elastic tubular conduit having a lumen, comprising:

- (a) four electrically operated valves, each valve being positionable adjacent to the conduit, each valve having a valve head, the valve head configured to alternate from a first position in which the lumen of the conduit adjacent to the valve head is unobstructed and a second position in which the lumen of the conduit adjacent to the valve head is obstructed;
- (b) a driver, configured to control the positions of the valve heads, so as to execute a predetermined temporo-spatial array of valve head positions; and
- (c) an anti-free flow device, which is operative to prevent the fluid flow through the conduit when the conduit is being inserted into or removed from the pump.

Dockum et al. “is generally related to blood pumping devices and, more particularly, to an implantable circulatory assist device and associated system for aiding or substituting heart action.” *See* Dockum et al. col. 1, lines 19-12.

Upton “relates to vacuum pumps in general, and vacuum pumps operated by piezoelectric elements in particular.” *See* Upton col. 1, lines 6-8.

Rejection of claims 1, 5-7, 9-11, 15 and 20

The Examiner has asserted on page 4 of the Office Action that “Dockum et al discloses a pump (see particularly Figs. 1, 3, 6a, 7 and 12) ... Fig. 12 discloses an anti-free flow device.”

However, Applicants respectfully submit that Dockum et al. fails to disclose, teach or suggest, *inter alia*, at least “an anti-free flow device, which is operative to prevent the fluid flow through the conduit when the conduit is being inserted into or removed from the pump,” as presently claimed. The Examiner has referred to Fig. 12 as disclosing an anti-free flow device, indicated in the telephone Interview as a “check valve” shown in Fig. 12. Applicants respectfully submit that Dockum et al. does not at all show an anti-free flow device, as recited in the present claims.

Applicants respectfully submit that Dockum et al.’s check valve is incapable of performing such functions, nor was it designed to perform such functions. Dockum et al. merely discloses “a split ring **126** engaging the inner surface of the prosthesis and deforming it outwardly for securing the prosthesis to the housing and securing the ring **126** in place. Pivotaly attached to the ring **126** is a disc valve **128** which is pivotaly connected thereto by a connecting tab **130** which functions to enable the disc valve to move from a closed position to an open position...The valve disc may be such that it will be received in alignment with the ring **126** with the ring **126** serving as a valve seat or the ring may have a continuous ledge engaged by the valve disc.” *See* Dockum et al. col. 6, lines 43-64; col. 7, lines 15-28; and Figs. 10-16.

Further, Dockum et al. discloses the “disc valve **128**” relative to an embodiment *different* from the embodiment referred to as supporting the pump elements referred to by numeral by the Examiner (*see* the first paragraph, lines 1-6, of page 4 of the Office Action, corresponding to elements discussed in col. 2, line 39, et seq. to col. 4, line 61; and Figs. 1-6 of Dockum et al.).

Indeed, the “disc valve **128**” shown by Dockum et al. is not only not an anti-free flow device as recited in the claims, but also not used within “a pump for generating fluid flow in an elastic tubular conduit having a lumen, comprising: a) *four electrically operated valves*, each valve being positionable adjacent to the conduit, each valve having a valve head, *the valve head configured to alternate from a first position in which the lumen of the conduit adjacent to the valve head is unobstructed and a second position in which the lumen of the conduit adjacent to the valve head is obstructed*; (b) *a driver, configured to control the positions of the valve heads, so as to execute a predetermined temporo-spatial array of valve head positions...*” (emphases added) as recited in the present claims.

In view of the Figures 10-16 of Dockum et al., it is clear that Dockum et al. fails to provide at least, the elements of an anti-free flow device, as recited in the present claims. Therefore, Dockum et al. fails to teach, suggest or show each and every element of the claims.

As admitted by the Examiner on page 4 of the Office Action, Dockum et al. is lacking in showing all of the features recited in the claims, and specifically, at least in that “Dockum et al does not disclose the same temporo-spatial array as shown in Fig. 4 or discuss the use of a battery as a power source.” These features are recited in independent claim 1.

For this reason, the Examiner applied Upton, asserting that “Upton discloses a similar deformable member pumping device having four valve/actuator elements A, B, C, D and a battery (col. 5 line 37). The valve elements are actuated in a successive manner (which can be determined by the graph portion of Fig. 4E) such as the temporo-spatial array as shown in Fig. 4 of the instant application. At the time of the invention it would have been obvious to one of ordinary skill in the art to utilize an actuation scheme as taught by Upton in the Dockum et al pump when four valves are being utilized in order to allow for the efficient pumping of a larger

quantity of fluid while ensuring sealing and flow in one direction. It also would have been obvious to utilize a battery as a well known power source which is stand-alone and does not require plugging into an outlet.” See page 4 of the Office Action. However, Upton is also **not** directed to “an *anti-free flow device*, which is *operative to prevent the fluid flow through the conduit when the conduit is being inserted into or removed from the pump*,” (emphases added) as recited in the claims. Indeed, Upton is silent, does not disclose, teach or suggest, and is thus non-enabling with regard to these features, *inter alia*.

Therefore, even *assuming arguendo* that Upton showed the temporo-spatial array or discusses the use of a battery as a power source, as asserted by the Examiner, as Upton has not been used to show “an anti-free flow device, which is operative to prevent the fluid flow through the conduit when the conduit is being inserted into or removed from the pump,” as recited in the claims, neither Upton nor the combination of Dockum et al. in view of Upton can cure the deficiencies of Dockum et al. It is respectfully submitted that Dockum et al. in view of Upton would not lead a person having ordinary skill in the art to the solution as described in the presently claimed subject matter. The combination of the cited prior art *fails* at least because the anti-free flow device, as claimed, is not disclosed, taught, or suggested by the cited prior art.

In view of the above discussion, Applicants respectfully submit that claim 1 is non-obvious and patentable over the cited prior art (Dockum et al. and Upton). Therefore, in view of the foregoing, reconsideration and withdrawal of the above rejection against claim 1 is respectfully requested.

As discussed above, by this Amendment, claims 6 and 20 have been canceled without prejudice or disclaimer to the contents thereto; accordingly the rejections to these claims are moot.

As claims 5, 7, 9-11 and 15 (and newly presented claims 21 and 22) depend from claim 1,

Applicants assert that claims 5, 7, 9-11, 15, 21 and 22 (including rejected claims 5, 7, 9-11 and 15) are allowable for at least their dependency from patentable claim 1, as well as for additional features recited therein. Accordingly, Applicants respectfully request reconsideration and withdrawal of the outstanding rejections.

Rejection of claims 16 and 17

The Examiner has relied on Brown to cure the deficiencies of Dockum et al. and Upton. See page 5 of the Office Action. However, Brown is also **not** directed to “an *anti-free flow device*, which is *operative to prevent the fluid flow through the conduit when the conduit is being inserted into or removed from the pump*,” (emphases added) as recited in the claims.

Accordingly, Brown fails to cure the deficiencies of Dockum et al. and Upton with respect to “an *anti-free flow device*, which is *operative to prevent the fluid flow through the conduit when the conduit is being inserted into or removed from the pump*,” as recited in independent claim 1 (emphases added) and discussed above.

Accordingly, the cited combination of Dockum et al., Upton and Brown, whether individually or in combination, fails to disclose, teach, or suggest, at least, “an *anti-free flow device*, which is *operative to prevent the fluid flow through the conduit when the conduit is being inserted into or removed from the pump*,” as recited in amended independent claim 1 (emphases added).

Dockum et al., Upton and Brown have been discussed above and each of these references does not disclose the features of claim 1 of the presently claimed subject matter. In addition, the combination of Dockum et al., Upton and Brown has been discussed above and does not disclose the features of claim 1 of the presently claimed subject matter. Thus, Applicants respectfully

submit that as none of the cited prior art has disclosed, taught or suggested the above features of the independent claim, such a claim is unobvious and therefore patentable.

As claim 16 and 17 depend from claim 1, Applicants assert that claims 16 and 17 are allowable at least for their dependency from patentable claim 1, as well as for additional features recited therein. Accordingly, Applicants respectfully request reconsideration and withdrawal of the outstanding rejection.

Rejection of claims 18 and 19

The Examiner has relied on Franetzki et al. to cure the deficiencies of Dockum et al. and Upton. *See* page 5 of the Office Action. However, Franetzki et al. is also **not** directed to “an *anti-free flow device*, which is *operative to prevent the fluid flow through the conduit when the conduit is being inserted into or removed from the pump*,” (emphases added) as recited in the claims.

Accordingly, Franetzki et al. fails to cure the deficiencies of Dockum et al. and Upton with respect to “an *anti-free flow device*, which is *operative to prevent the fluid flow through the conduit when the conduit is being inserted into or removed from the pump*,” as recited in independent claim 1 (emphases added) and discussed above.

Accordingly, the cited combination of Dockum et al., Upton and Franetzki et al., whether individually or in combination, fails to disclose, teach, or suggest, at least, “an *anti-free flow device*, which is *operative to prevent the fluid flow through the conduit when the conduit is being inserted into or removed from the pump*,” as recited in amended independent claim 1 (emphases added).

Dockum et al., Upton and Brown have been discussed above and each of these references does not disclose the features of claim 1 of the presently claimed subject matter. In addition, the

combination of Dockum et al., Upton and Franetzki et al. has been discussed above and does not disclose the features of claim 1 of the presently claimed subject matter. Thus, Applicants respectfully submit that as none of the cited prior art has disclosed, taught or suggested the above features of the independent claim, such a claim is unobvious and therefore patentable.

As claim 18 and 19 depend from claim 1, Applicants assert that claims 16 and 17 are allowable at least for their dependency from patentable claim 1, as well as for additional features recited therein. Accordingly, Applicants respectfully request reconsideration and withdrawal of the outstanding rejection.

Newly presented claims 21 and 22

Applicants respectfully submit that newly presented claim 21 is patentable over the cited prior art, whether alone or in combination. Indeed, none of the cited documents shows an anti-free flow device as recited in independent claim 1, and therefore cannot show the further features of the anti-free flow device as recited in claim 21, "wherein the anti-free flow device is configured to press upon the conduit so as to occlude the lumen when the device is not inside the pump, and to open when the conduit is inside the pump." Thus, Applicants believe that newly introduced claim 12 is new and non obvious over the prior art.

Regarding newly introduced claim 22, in Applicants' opinion this claim is patentable over the available prior art at least for the reasons stated above with respect to 21. Moreover, it is to be noted that claim 22 not only recites the pump according to claim 21, but further recites that "the anti-free flow device comprises: a sleeve, which contains a portion of the tube; and a lever, which is biased by a spring to a position in which the lever presses against the conduit, and which is depressed away from the spring-biased position so as to open the lumen when the sleeve is

positioned in the pump.” These additional features further underscore and distinguish the differences between the claimed subject matter and the cited prior art. Thus, Applicants believe that newly introduced claim 12 is new and non obvious over the prior art.

Allowable Subject Matter

The Examiner has indicated that claims 12 and 13 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph (dependent upon a rejected base claim), including all of the limitations of the base claim and any intervening claims.

Response

Applicants thank the Examiner for his careful consideration of the claims and indication of Allowable Subject Matter. Applicants have followed the Examiner’s suggestions and indication of allowable subject matter in the above discussed claim amendments.

With this Response, Applicants present amended claims 12 and 13. Amended claim 12 presents the Examiner indicated allowable subject matter of original claim 12 in independent form, including the claimed subject matter of independent claim 1. Similarly, amended claim 13 presents the Examiner indicated allowable subject matter of original claim 13 in independent form, including the claimed subject matter of independent claim 1.

Accordingly, Applicants request an early indication of allowability of the above discussed claims.

CONCLUSION

In light of the foregoing, Applicants submits that the application is now in condition for allowance. If the Examiner believes the application is not in condition for allowance, Applicants respectfully requests that the Examiner call the undersigned attorney(s).

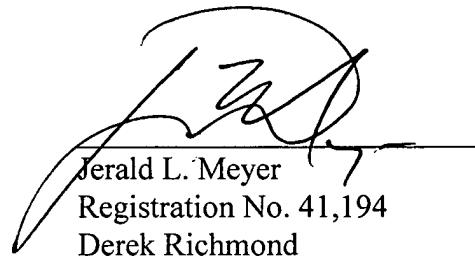
In the event this paper is not timely filed, Applicants petition for an appropriate extension of time. Please charge any fee deficiency or credit any overpayment to Deposit Account No. 14-0112.

Respectfully submitted,

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